The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 62

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

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Ex parte DANIEL J. CAPON, ARTHUR WEISS, BRYAN A. IRVINANDINTERFERENCES

MARGO R. ROBERTS and KRISZTINA ZSEBO

U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
RVINAND INTERFERENCES

Appeal No. 2004-0274 Application No. 08/238,4051

ON BRIEF

Before WINTERS, GRON and NAGUMO, <u>Administrative Patent Judges</u>.

GRON, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL UNDER 35 U.S.C. § 134 and ORDER

Application for patent filed May 5, 1994. According to applicants, this application is a CIP of Application 07/988,194, filed December 9, 1992, now U.S. Patent 5,359,046, patented October 25, 1994; which is said to be a CIP of Application 07/627,643, filed December 14, 1990, abandoned; and a CIP of PCT/US91/09431, filed December 12, 1991.

This is an appeal under 35 U.S.C. § 134 from an examiner's final rejections of Claims 57, 64, 65, 67 and 69 of Application 08/238,405, filed May 5, 1994. Pending Claims 57, 59, 64, 65, 67 and 69 are reproduced in the Appendix to Appellant's Brief (AB). Claim 59, which depends from Claim 57, is not rejected. Thus, it is not before us.

This case is not ripe for appeal. We have carefully considered the appealed rejections and the supporting record. As we explain at length <u>infra</u>, we find no clear statement of the scope and content of the claims. To the extent claim language has been interpreted by either the examiner or applicants, neither has explained how and why that interpretation is supported by the specification. Moreover, both have defined and used terms inconsistently. The record before us, or at least our understanding of the record, does not provide an adequate basis for us to reasonably construe the claim language, determine the scope and content of the claimed invention, and evaluate the merits of the appealed rejection on our own. Accordingly, we express no opinion on the merits of the appealed rejections and remand this case for further prosecution not inconsistent with the following discussion.

Rejections

Claims 57, 64, 65, 67 and 69 stand rejected for unpatentability under 35 U.S.C. § 112, first paragraph, because the specification as originally filed allegedly does not provide an adequate written description of the subject matter now claimed. Claims 64, 65, 67 and 69 stand or fall together with Claim 57 under 35 U.S.C. § 112, first paragraph (Appellant's Brief, page 9 (AB9)).

Claims 57, 64, 67 and 69 stand rejected as unpatentable under 35 U.S.C. § 102(e) over Eshar et al (Eshar), U.S. Patent 5,906,936, issued May 25, 1999, from Application 08/055,396, filed May 4, 1993. Claims 64, 67 and 69 stand or fall together with Claim 57 under 35 U.S.C. § 102(e)(AB9).

Discussion

1. Rejection Under § 112, First Paragraph (Written Description)

"The PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."

In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976);

In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618

(Fed. Cir. 1989). In this appeal, the examiner's rejection is based on the following rationale (Examiner's Answer, p. 3 (EA3)):

Claims 57, 64-65, 67 & 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner found in the specification as originally filed no express "antecedent basis" for, nor "conception" of, a chimeric protein of Claim 57 which functions "in the absence of a T-cell receptor" (EA4). The examiner appears to believe that finding, or lack thereof, is sufficient to shift the PTO's initial burden to applicants to prove that they had possession of the full scope of the invention now claimed at the time they filed their application. However, the examiner has been remiss in interpreting what the term "T-cell receptor" in Claim 57 would have meant to persons skilled in the art and, accordingly, has left the phrase "in the absence of a T-cell receptor" open to various interpretations. Thus, the scope and content of the presently claimed subject matter, including the newly added negative limitation, remain unclear. Significantly, the examiner has not distinguished the scope and content of the subject matter encompassed by Claim 57, including the added negative limitation, from the scope and content of the subject matter of Claim 57, without the added negative limitation. Rather, the examiner

points to a paragraph bridging pages 30-31 of applicants' original specification for (EA4) (examiner's emphasis):

. . . the proper context . . . that a "CD8/ζ" chain can be used as the cytoplasmic signaling domain in a Jurkat T cell leukemic line, JRT3.T3.5, which contains a mutated and non-functional T-cell receptor, and therefore, results "in the absence of TCR [T-cell receptor] expression on the cell surface . . ." In other words, a mutated T-cell receptor still exists in these cells, which does not become functional, and presumably is not expressed on the cell surface, until the $\zeta(\text{zeta})$ chain is added. Therefore, the generic recitation of excluding any T-cell receptors (i.e., including mutated T-cell receptors) from cells that must be used to construct the chimeric protein of the instant invention was not reasonably contemplated at the time of filing Appellants' invention; thereby constituting new matter.

Note that if claim 57 recited "in the absence of a wildtype T-cell receptor expressed on the cell surface... wherein said cytoplasmic domain consists of a zeta chain, and when said protein is then expressed as a membrane bound protein...", this rejection would have been obviated. . . .

The examiner responds to the arguments in appellant's brief as follows (EA7):

[T]he issue is simply that pages 30-31 of the specification solely appear to contemplate transfection of the $\zeta(\text{zeta})$ chain of the "Tc receptor [CD3]" in a mutated T-cell Jurkat cell line, where the issue then becomes whether the generic negative limitation of "in the absence of a T cell receptor" is properly contemplated in order to overcome the previously cited 102(b) art . . .

Instead of interpreting the significance of the added negative limitation and defining the scope and content of the subject matter claimed therewith, the examiner finds that an example in appellant's specification of an inactive, mutated

T-cell receptor activated by the addition of a $\zeta(\text{zeta})$ chain does not support the subject matter now claimed, i.e., does not establish that applicants "had possession" of the subject matter claimed at the time the application was filed (EA3).

The PTO has not satisfied its initial burden of presenting evidence or reasons why persons skilled in the art would not have recognized in the specification as originally filed a description of the subject matter defined by Claim 57 on appeal for several reasons. First, because the examiner did not determine what the negative limitation "in the absence of a T-cell receptor" means or how the claimed subject matter differs with and without the added negative limitation, we are left to speculate as to the scope and content of the subject matter presently claimed without any benefit of the examiner's claim interpretation, applicants' intent, or the prior knowledge and skill in the art. axiomatic that issues involving the patentability of claimed subject matter under 35 U.S.C. § 112, first paragraph, 35 U.S.C. § 102, and 35 U.S.C. § 103 cannot, and properly should not, be considered until the scope and content of the subject matter claimed has been determined. <u>In re Moore</u>, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971), instructs at 1235, 169 USPQ at 238:

[T]he claims must be analyzed first in order to determine exactly what subject matter they encompass.

The first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

"Once having ascertained exactly what subject matter is being claimed, the next inquiry must be into whether such subject matter is novel." In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970). "Before considering the rejections under 35 U.S.C. §§ 103 and 112, we must first decide . . . [what] the claims include within their scope." In re Geerdes, 491 F.2d 1260, 1262, 180 USPQ 789, 791 (CCPA 1974). It is improper to analyze the claimed subject matter and consider the merits of rejections under 35 U.S.C. § 103 and 112 "relying on what at best are speculative assumptions as to the meaning of the claims."

In re Steele, 305 F.2d 859, 862-863, 134 USPQ 292, 295 (CCPA 1962).

Next, the examiner seems to have equated the chimeric protein of Claim 57 to one produced by Eshar's transfection of "TcR deficient mutant (27J)" (Eshar, col. 9, 1. 64). The examiner, however, points to no evidence in support of, and proffers no explanation for, the finding that Eshar's transfected "TcR deficient mutant (27J)" is identical or substantially

identical to the invention applicants claim in kind and indicated function.

A finding by the examiner that the specification does not satisfy the description requirement of 35 U.S.C. § 112, first paragraph, for the full scope of the subject matter claimed must be based on consideration of the specification as a whole. Wright, 866 F.2d 422, 424, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989). Here, the examiner cites pages 30-31 of the specification as basis for the argument that applicants did not originally have possession of the subject matter now claimed (EA3). That focus suggests that the examiner's finding that applicants' supporting specification does not provide a written description of the invention claimed is based essentially on applicants' Example 1. Needless to say, the disclosure of the specification before us is not limited to Example 1 thereof. The examiner never mentioned the specification's description of cytoplasmic domains which appear to be operational in the absence of a T-cell receptor (Specification, p. 4, 1. 12-17):

The zeta chain is also expressed on natural killer cells as part of the Fc γ RIII receptor. The gamma chain of the Fc ϵ receptor is closely related to the zeta, and is associated with the Fc ϵ RI receptor of mast cells and basophils and the C16 receptor expressed by macrophages and natural killer cells.

The examiner appears not to have considered any of the specification's more general teachings related to non-TCRs and signal transduction thereby (Specification, p. 7, 1. 9-34):

The triggering of signal transduction leading to cytotoxic function by different cells of the immune system can be initiated by chimeric receptors with antibody type specificity. These chimeric receptors by-pass the requirement for matching at the MHC locus between target cell (i.e. virally infected, tumor cell, etc.) and effector cell (i.e., T cell, granulocyte, mast cell, Intracellular signal transduction or cellular activation is achieved by employing chimeric proteins having a cytoplasmic region associated with transduction of a signal and activation of a secondary messenger system, frequently involving a kinase, and a non-MHC restricted extracellular region capable of binding to a specific ligand and transmitting to the cytoplasmic region the formation of a binding complex. Particularly, cytoplasmic sequences of the zeta, eta, delta, gamma and epsilon chains of TCR and the gamma chain of Fc,R1, or a tyrosine kinase are employed joined to other than the natural extracellular region by a transmembrane domain, and the cytoplasmic region is not naturally joined to an extracellular ligand-binding In this manner, cells capable of expressing the chimeric protein can be activated by contact with the ligand, as contrasted with the normal mode of activation for the cytoplasmic portion.

The examiner appears to have ignored all the specification's teachings that the invention may find applications with cells other than T-cells that are capable of killing target cells:

The subject invention may find application with cytotoxic lymphocytes (CTL), Natural killer cells (NK), tumor-infiltrating-lymphocytes (TIL) or other cells which are capable of killing target cells when activated. . . . By providing a receptor extracellular domain, e.g., CD4, which binds to a surface marker of a pathogen or neoplastic condition, . . . the cells may serve as therapeutic agents. . . Alternatively, one may isolate and transfect host

cells with the subject constructs and then return the transfected host cells to the host.

(Specification, pp. 21-22, bridging para.);

In addition, suitable host cells include hematopoietic stem cells, which develop into cytotoxic effector cells with both myeloid and lymphoid phenotype including granulocytes, mast cells, basophils, macrophages, natural killer (NK) cells and T and B lymphocytes. . . . The zeta subunit of the T cell receptor is associated not only with T cells, but is present in other cytotoxic cells derived from hematopoietic stem cells. Three subunits, zeta, eta and the gamma chain of the Fc& receptor, associate to form homodimers as well as heterodimers in different cell types derived from stem cells. The high level of homology between zeta, eta and the gamma chain of the Fc_{ϵ} receptor, and their association together in different cell types suggests that a chimeric receptor consisting of an extracellular binding domain coupled to a zeta, eta or gamma homodimer, would be able to activate cytotoxicity in various cell types derived from hematopoietic stem For example, zeta and eta form both homodimers and heterodimers in T cells . . . ; zeta and the gamma chain of the Fc ϵ receptor form homodimers and heterodimers in NK cells and function to activate cytotoxic pathways initiated by engagement of Fc receptors . . . ; the gamma chain forms homodimers expressed in monocytes and macrophages . . . ; and zeta and the gamma chain are used by the IgE receptors (FcRI) in mast cells and basophils . . . for signaling cells to initiate cytotoxic function.

(Specification, p. 22, l. 26, to p. 23, l. 29; citations omitted).

Put simply, the examiner seems not to have considered the specification's teaching as a whole. Interestingly, the examiner did not reject dependent Claim 59 under 35 U.S.C. § 112, first paragraph, as lacking written descriptive support in the original specification. Why?

We find in the original specification no reasonable basis for the examiner's apparent view that the absence of wildtype T-cell receptors from Claim 57 (EA4) would obviate the new matter rejection. Why does the "T-cell receptor" excluded from Claim 57 read on functional wildtype T-cell receptors and nonfunctional mutant T-cell receptors (Eshar, col. 9, 1. 64) and yet not read on functional T-cell receptor subunits "selected from the group consisting of the CD3 zeta chain, the CD3 eta chain, the CD3 gamma chain, the CD3 delta chain, [and] the CD3 epsilon chain . . . " (Claim 57). We are more confused than aided by the examiner's answer.

The examiner's focus on applicants' Example 1 in finding that the original specification did not include an adequate written description of the full scope of the subject matter presently claimed suggests that the examiner perceives a direct correlation between the scope of subject matter applicants actually reduced to practice and/or applicants' compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, and applicants' compliance with the description requirement of 35 U.S.C. § 112, first paragraph. To the contrary, our reviewing court has repeatedly espoused the view that the description and enablement requirements of 35 U.S.C. § 112, first paragraph, are distinct. Vas-Cath Inc. V. Mahurkar, 935 F.2d 1555, 1564,

19 USPQ2d 1111, 1117 (Fed. Cir. 1991). "[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not <u>describe</u> that invention." <u>DiLeone</u>, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). Moreover, the kind and number of embodiments of the claimed subject matter in the specification may not be dispositive of compliance with either requirement. Evidence in the specification which shows that the inventor "had possession" of an embodiment of the claimed invention does not necessarily establish that the inventor was "in possession" of the claimed invention, i.e., evidence showing actual reduction to practice of subject matter within or outside the scope of the claims does not establish compliance or noncompliance with the written description requirement of 35 U.S.C. § 112, first paragraph. Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1616-1617 (Fed. Cir. 2002); Lockwood v. American <u>Airlines, Inc.</u>, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). As said in Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d at 1325, 63 USPQ2d at 1613:

Application of the written description requirement . . . is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the <u>statutory</u> mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the

specification does not adequately describe the claimed invention. . . .

Similarly, we conclude that proof of a reduction to practice, absent an adequate description in the specification of what is reduced to practice, does not serve to describe or identify the invention for purposes of § 112, . . . [paragraph] 1. As with "possession," proof of reduction to practice may show priority of invention or allow one to antedate a reference, but it does not by itself provide a written description in the patent specification.

"[D]uring prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed." In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). In this case, the examiner and applicants have not endeavored to explore and define the scope and content of the claimed subject matter presently before us. Moreover, the examiner does not appear to have considered whether applicants' specification as a whole would have described the subject matter encompassed by applicants' claims to a person skilled in the art. We might rule that the PTO has not met its initial burden of presenting adequate evidence or reasons establishing that persons skilled in the art would not have recognized in the original disclosure a description of the invention defined by the claims before us, and rest. On this record, however, we are concerned that persons skilled in the art may not be able to understand the full scope

and content of the subject matter encompassed by the present claims. Accordingly, we believe the better course is to remand this case to the examiner for claim interpretation and subsequent prosecution consistent with the views expressed above.

2. Rejection Under § 102 Over Eshar

Claims 57, 64, 67 and 69 stand rejected under 35 U.S.C. \$ 102(e) as anticipated by Eshar et al (Eshar), U.S. Patent 5,906,936, which issued May 25, 1999, from Application 08/055,396, filed May 4, 1993. Claims 64, 67 and 69 stand or fall together with Claim 57 (AB9).

The examiner finds that the original specification discloses (EA4):

[A] "CD8/ ζ " chain can be used as the cytoplasmic signaling domain in a Jurkat T cell leukemic line, JRT3.T3.5, which contains a mutated and non-functional T-cell receptor, and therefore, results "in the absence of TCR expression on the cell surface . . ." In other words, a mutated T-cell receptor still exists in these cells, which does not become functional, and presumably is not expressed on the cell surface, until the ζ (zeta) chain is added.

According to the examiner, Claim 57, even with the negative limitation "in the absence of a T-cell receptor," encompasses a chimeric protein expressed by a nonfunctional, mutated T-cell Jurkat cell line rendered functional by the addition of a CD3 ζ (zeta) chain. Eshar describes a transfected TcR deficient mutant (J27) cell line and a OVB3 anti-human ovarian carcinoma

cell line rendered functional by Fc receptor bearing T-cells (Eshar, col. 9, 1. 58, to col. 10, 1. 43; and col. 3, 1. 21-28, describing Fig. 6). Without explanation, the examiner finds that Claims 57, 64, 67 and 69 are anticipated by Eshar. To the contrary, appellant argues that Eshar nowhere describes or reasonably suggests a functional chimeric protein of applicants' Claim 57 expressed on the surface of a host cell "in the absence of a T-cell receptor" (AB19, last seven lines).

Again, we are confused. Eshar teaches that "the cytotoxic T cell hybridoma MD45 or a TcR deficient mutant (27J) . . . isolated from the MD45 hybridoma" was used for transfection (Eshar, col. 9, 1. 62-65). We note, however, that the chimeric protein of Claim 57 must be expressed as a membrane bound protein in a host cell and "said membrane bound protein initiates signaling in said host cell once the extracellular domain binds to said antigen" (Claim 57, last clause), i.e., the chimeric protein must signal activation of the host cell "in the absence of a T-cell receptor" (Claim 57, the "cytoplasmic domain" thereof). The examiner points to no evidence that Eshar's transfected "TcR deficient mutant (27J)" signals activation of the host cell "in the absence of a T-cell receptor" as Claim 57 requires (Claim 57, "cytoplasmic domain"). The examiner did not

mention Eshar's reference to a OVB3 anti-human ovarian carcinoma cell line rendered functional by Fc receptor bearing T-cells.

We are no less confused by appellant's view that the cytoplasmic domain of the chimeric protein of Claim 57 on appeal may comprise the CD3 zeta chain, the CD3 eta chain, the CD3 gamma chain, the CD3 delta chain, the CD3 epsilon chain, or homologue thereof, or the gamma chain of the Fc receptor or tyrosine kinase "of T-cell receptor" (AB, p. 19, first full para.). Appellant inconsistently argues that chimeric proteins, which signal activation of a host cell, "operate independent of a T-cell receptor as signaling molecules" (AB, p. 16, last full para.). How does a host cell comprising the CD3 zeta chain, the CD3 eta chain, the CD3 gamma chain, the CD3 delta chain, or the CD3 epsilon chain "of T-cell receptor", or homologues thereof, operate independent of a T-cell receptor as signaling molecules? Moreover, Eshar appears to teach a OVB3 anti-human ovarian carcinoma cell line which operates by the gamma chain of the Fc receptor or tyrosine kinase (Eshar, col. 10, 1. 12-16; col. 3, 1. 21-28 ("Fig. 6 shows . . . 2 peaks[,] the first negative, the second due to Fc receptor bearing T cells")), i.e., independent of a T-cell receptor as signaling molecules?

On this record, we are unable to determine why T-cell receptor chains which signal activation of a host cell operate

independent of a T-cell receptor and why Fc receptor bearing T-cells which signal activation of a host cell by the Fc receptor depend on the T-cell receptor to function. We are unable to determine how T-cell receptor chains which signal activation of a host cell operate independent of a T-cell receptor and how an Fc receptor which itself signals activation of a host cell depends on the T-cell receptor to function.

The examiner appears to concede that applicants' original specification describes a cytoplasmic domain consisting of the CD3 zeta chain, which is active in the absence of a wild-type T-cell receptor (EA4, last para.):

Note that if claim 57 recited "in the absence of a wildtype T-cell receptor expressed on the cell surface... wherein said cytoplasmic domain consists of a zeta chain, and when said protein is then expressed as a membrane bound protein...", this rejection would have been obviated. . . .

However, the examiner has not explained that finding, and appellant does not appear to agree. The respective positions raise this case to new levels of confusion.

This case is not ripe for appeal. We deem it best to return it to the examiner for further prosecution. There, the "claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed."

In re Zletz, 893 F.2d at 321, 13 USPQ2d at 1322. "An essential

purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous." Id.

[T]he inquiry during examination is patentability of the invention as "the applicant regards" it [(35 U.S.C. § 112, second para.)], and if the claims do not "particularly point[] out and distinctly claim[]", in the words of section 112, that which examination shows the applicant is entitled to claim as his invention, the appropriate PTO action is to reject the claims for that reason.

<u>In re Zletz</u>, 893 F.2d at 321, 13 USPQ2d at 1322.

We may not read limitations into claims which are contrary to their plain words. We may not read limitations into claims which are contrary to the interpretation that the inventor himself placed on the claims. Id. Where, as here, there is no explicit antecedent basis for a negative limitation in the claims, and the examiner seems to interpret the scope and content of the claims relative only to an example of applicants' invention, the examination process has not performed its essential purpose.

Only after the claims have been construed and their scope and content have been determined can persons skilled in the art and patent examiners consider the questions whether the subject matter applicants regard as their invention was previously described by (35 U.S.C. § 102), and/or would have been obvious to persons having ordinary skill in the art in view of (35 U.S.C.

§ 103), prior art. If on this record the claims are vague and indefinite and defy construction, a rejection under 35 U.S.C. § 112, second paragraph, may be in order. Here, the examination process has proceeded out of order. We have before us a road map without a key.

3. Other issues

Claim 57 and dependent Claim 59 are drawn to chimeric proteins. The chimeric protein of Claim 57 comprises in the N-terminal to C-terminal direction: an extracellular antigenbinding domain of a single chain antibody that binds specifically to an antigen; a transmembrane domain; and a cytoplasmic domain which initiates a signal resulting in activation of a secondary messenger system in the absence of a T-cell receptor selected from the group consisting of the CD3 zeta chain, the CD3 eta chain, the CD3 gamma chain, the CD3 delta chain, the CD3 epsilon chain, and homologue thereof, the gamma chain of the Fc receptor and tyrosine kinase; and when said chimeric protein is expressed as a membrane bound protein in a selected mammalian host cell under conditions suitable for expression, said membrane bound protein initiates signaling in said host cell once the extracellular domain binds to said antigen. Claims 64, 65, 67 and 69 are directed to mammalian cells comprising as a surface membrane a chimeric protein of Claim 57.

The examiner should first interpret the meaning of the claim language and determine the full scope and content of the subject matter claimed. If the scope and content of the subject matter claimed cannot be determined with particularity from the existing record, the examiner should consider whether a rejection of applicants' claims under 35 U.S.C. § 112, second paragraph, is appropriate. After the subject matter claimed is ascertained with particularity, the examiner may wish to consider whether applicants' specification otherwise satisfies the written description and enablement requirements of 35 U.S.C. § 112, first paragraph. It appears from this specification, and the specifications of its parent and related applications, that knowledge of the structure, formula, chemical name, and physical properties of DNA which encodes the claimed chimeric proteins, in addition to the properties of the chimeric protein encoded, may be necessary to adequately describe, and enable one skilled in the art to express, the full scope of the functional chimeric proteins applicants now generally claim as surface membrane proteins of mammalian host cells. While we are mindful that genetic material does not appear to be claimed, we see no distinction between the patentability under 35 U.S.C. § 112, first paragraph, of claims directed to functional chimeric proteins encoded by DNA and expressed as mammalian host cell

surface membrane proteins and and claims directed to DNA which encodes expression of functional chimeric proteins as mammalian host cell surface membrane proteins, or between claims directed to mammalian cells comprising chimeric surface membrane proteins and claims directed to mammalian cells comprising DNA which encodes chimeric surface membrane proteins.

While we might in this case exercise our authority to enter new grounds of rejection under 37 CFR § 1.196(b), we prefer to remand the case for further prosecution. The pending claims and the prior art cited against the subject matter claimed require interpretation and technical fact-finding which normally evolves from the examination process. While the Board of Patent Appeals and Interferences may enter new grounds of rejection, we normally do so only when the proper construction of the claims is clear. We are not inclined to substitute new grounds of rejection for standing rejections not ripe for appeal. Our primary function is to review twice rejected claims. 35 U.S.C. § 134. It is only in unusual circumstances that we elect to bypass the conventional administrative process with its essential purpose of fashioning. claims that are precise, clear, correct, and unambiguous. In re Zletz, 893 F.2d at 321, 13 USPQ2d at 1322.

<u>Order</u>

Upon consideration of the entire record before us, it is ORDERED that this application is remanded to the examiner for further prosecution consistent with the views expressed herein.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR \$ 1.136(a).

REMANDED

SHERMAN D. WINTERS

Administrative Patent Judge

TEDDY S. GRON

Administrative Patent Judge

BOARD OF PATENT

APPEALS

AND

INTERFERENCES

MARK NAGUMO

Administrative Patent Judge

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